

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST  
LABORATORIES HOLDINGS, LTD., MERCK  
KGaA and MERCK PATENT GESELLSCHAFT  
MIT BESCHRÄNKTER HAFTUNG,

Plaintiffs,

V.

ACCORD HEALTHCARE INC., et al.,

Defendants.

C.A. No. 15-272 (GMS)  
**CONSOLIDATED**

FOREST LABORATORIES, LLC, FOREST  
LABORATORIES HOLDINGS, LTD., MERCK  
KGaA and MERCK PATENT GESELLSCHAFT  
MIT BESCHRÄNKTER HAFTUNG,

Plaintiffs,

V.

ALEMBIC PHARMACEUTICALS LTD., et al.,

Defendants.

C.A. No. 15-273 (GMS)

**STIPULATION AND [PROPOSED] ORDER**

The Court, upon the consent and request of Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Merck KGaA and Merck Patent Gesellschaft Mit Beschränkter Haftung (collectively, “Plaintiffs”), and Defendants Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, “Alembic”), hereby acknowledges the following Stipulation and issues the following Order.

### **STIPULATION**

1. This Court has subject matter jurisdiction over the above-captioned patent infringement actions (the “Actions”) and personal jurisdiction over Plaintiffs and Alembic for purposes of the Actions. Venue is proper in this Court as to Plaintiffs and Alembic for purposes of the Actions.

2. In the Actions, Plaintiffs have asserted claims against Alembic for infringement of U.S. Patent Nos. 7,834,020 (“the ‘020 Patent”), 8,193,195 (“the ‘195 Patent”), 8,236,804 (“the ‘804 Patent”), and 8,673,921 (“the ‘921 Patent”) (collectively the “Patents in Suit”) in connection with Alembic’s submission of Abbreviated New Drug Application (“ANDA”) 208202 directed to generic vilazodone hydrochloride 10, 20 and 40 milligram tablet products to the U.S. Food and Drug Administration (“FDA”).

3. In response to Plaintiffs’ claims of patent infringement, Alembic has alleged certain defenses and counterclaims, including that the Patents in Suit are invalid. To date, no final judgment has been entered by this Court regarding Plaintiffs’ claims or Alembic’s defenses or counterclaims.

4. For purposes of the Action, Alembic admits that submission of ANDA 208202 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and/or sale of the generic vilazodone hydrochloride 10, 20 and 40 milligram tablet products within the United States before the expiration of the Patents in Suit was an act of infringement of the Patents in Suit under 35 U.S.C. § 271(e)(2)(A), and further stipulates to the enforceability and validity of the Patents in Suit.

5. By this Stipulation and Order, the Parties agree that all other claims, defenses, counterclaims set forth in the pleadings in the Actions, including allegations and averments contained therein, should be dismissed, without prejudice.

**ORDER**

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiffs and Alembic, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 208202 was a technical act of infringement of the Patents in Suit under 35 U.S.C. § 271(e)(2)(A). No decision in the Actions has been obtained by either party regarding the validity of the Patents in Suit and/or whether any commercial making, using, selling, or offering to sell within the United States, or importing into the United States, of the generic products described by ANDA No. 208202 would infringe those patents.

2. All other claims, defenses, and counterclaims set forth in Plaintiffs' and Alembic's pleadings against each other in the Actions, including the allegations and averments contained therein, are hereby dismissed, without prejudice.

3. Absent a license or other authorization by Plaintiffs, Alembic, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the generic vilazodone hydrochloride 10, 20 and 40 milligram tablet products that are the subject of ANDA 208202 or any other ANDA that references New Drug Application 022567 and for which VIIBRYD® is the reference listed drug during the life of the Patents in Suit, including any extensions and pediatric exclusivities unless and until all of the claims of the Patents in Suit are found invalid or unenforceable by a court decision from which no appeal has been or can be taken.

4. Plaintiffs and Alembic each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Plaintiffs and Alembic for purposes of enforcing this Stipulation And Order.

6. This Stipulation And Order shall finally resolve the Actions between Plaintiffs and Alembic.

7. Nothing herein prohibits or is intended to prohibit Alembic from maintaining a "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to any of the Patents in Suit.

8. Each party shall bear its own costs and fees incurred in connection with the Actions.

9. The Clerk of the Court is directed to enter this Stipulation And Order in the above-captioned Actions forthwith.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

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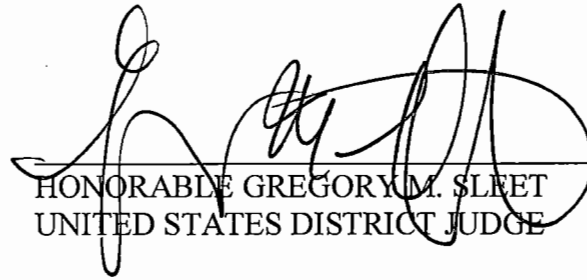
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Pharmaceuticals Ltd., Alembic Global Holding  
SA and Alembic Pharmaceuticals, Inc.*

**SO ORDERED:**

This 2<sup>nd</sup> day of <sup>May</sup>~~April~~, 2017



HONORABLE GREGORY M. SLEET  
UNITED STATES DISTRICT JUDGE